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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/527,844	03/17/00	BARBERICH	T 4821-334-999

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HM22/0625

EXAMINER

BAHAR, M

ART UNIT	PAPER NUMBER
1617	5

DATE MAILED: 06/25/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

**Office Action Summary**

Application No.

09/527,844

Applicant(s)

BARBERICH ET AL.

Examiner

Mojdeh Bahar

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-49 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-15, drawn to a method of treating or preventing a disorder ameliorated by the inhibition of serotonin reuptake at 5-HT<sub>2</sub> receptors and/or inhibition of dopamine reuptake at dopamine D<sub>2</sub> receptors which comprises administering to a patient in need of such treatment a therapeutically effective amount of a ziprasidone metabolite, classified in class 514, subclass 254.04.
- II. Claims 16-45, drawn to a pharmaceutical composition and dosage form comprising a ziprasidone metabolite, classified in class 514, subclass 254.04.
- III. Claims 46-47, drawn to a method of preparing ziprasidone sulfoxide which comprises treating ziprasidone with one molar equivalent of an oxidizing agent, class 544, subclass 367.
- IV. Claims 48-49, drawn to a method of preparing ziprasidone sulfone which comprises treating ziprasidone with two molar equivalents of an oxidizing agent, class 544, subclass 367.

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process of treating a neuroleptic disorder, e.g., seizure, can be practiced with a composition or dosage form containing phenytoin.

Inventions I, III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the invention in Group I has a different function than the inventions in Groups III and IV because Group I is drawn to a method of treating or preventing a disorder ameliorated by the inhibition of serotonin reuptake at 5-HT<sub>2</sub> receptors and/or inhibition of dopamine reuptake at dopamine D<sub>2</sub> receptors which comprises administering to a patient in need of such treatment, whereas Groups III and IV are drawn to methods of preparing the compounds, ziprasidone sulfoxide and sulfone respectively. The invention of Group III is unrelated to the invention of Group IV because they have different functions. Group III is drawn to a method of preparing ziprasidone sulfone employing one molar equivalent of an oxidizing agent, whereas Group IV is drawn to a method of preparing ziprasidone sulfoxide employing two molar equivalent of an oxidizing agent.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

### *Specie Election*

If applicant elects the invention of Group I a further election of species is required.

This application contains claims directed to the following patentably distinct species of disorder ameliorated by the inhibition of serotonin reuptake at 5-HT<sub>2</sub> receptors and/or inhibition of dopamine reuptake at dopamine D<sub>2</sub> receptors.

The treatment of each disorder ameliorated by the inhibition of serotonin reuptake at 5-HT2 receptors and/or inhibition of dopamine reuptake at dopamine D2 receptors represents a separate field of medical technology having a separate, non-coextensive field of search. The treatment for migraines differs from that of Parkinson's disease. Similarly, the treatment of intractable hiccups is not the same as the treatment of epilepsy. The search for all the disorders/conditions encompassed by disorders ameliorated by the inhibition of serotonin reuptake at 5-HT2 receptors and/or inhibition of dopamine reuptake at dopamine D2 receptors above is therefore an undue burden on the office. Note that the search is not limited to the patent files.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-15 are generic.

Applicant is advised that in order for the reply to this requirement to be complete it must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Because the above restriction/election requirement is complex, a telephone call to the applicant's agent to request an oral election was not made. See M.P.E.P. Sec 812.01.

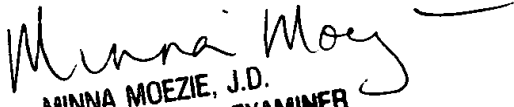
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The examiner can normally be reached on (703) 305-1007 from 8:30 a.m. to 6:30 p.m. Monday, Tuesday, Thursday and Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Mojdeh Bahar  
Patent Examiner  
June 7, 2001

  
MINNA MOEZIE, J.D.  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600